American Association of
HEALTH PLANS

December 19, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 02N-0417

Dear Sir/Madam:

I am writing on behalf of the American Association of Health Plans (AAHP) to respond to the Food and Drug Administration's (FDA) October 24, 2002 proposed regulation amending patent listing requirements and rules for application of 30-month stays on approval of abbreviated new drug applications (67 FR 65448). AAHP is the principal national organization representing HMOs, PPOs, and other network-based health plans. We represent approximately 1,000 health plans caring for more than 170 million Americans throughout the United States. AAHP's member plans face challenges in offering affordable, clinically appropriate prescription drug benefits for consumers as part of their benefit packages. In the face of steeply rising prescription drug spending trends, they are directly affected by rules governing the availability of generic drugs that can contribute to efforts to make safe, less costly alternatives to brand name drugs available to consumers.

We support the goal of the proposed rule to reduce the potential for inappropriate delays in the approval of new drug applications for generic drugs by revising certain requirements related to these applications. These provisions grow out of recommendations included in a recent report from the Federal Trade Commission.[1]

Value of prescription drugs to consumers. We believe that the FDA's efforts to improve rules for bringing generic drugs into the marketplace can contribute to accessibility of beneficial prescription drugs to consumers. Numerous studies have demonstrated that the appropriate use of prescription drugs has improved and saved countless lives. The National Institutes of Health has reported that innovation in the pharmaceutical industry has prolonged life expectancies and increased productivity.[2] Other studies demonstrate that innovations in prescription drugs have saved the health care system billions of dollars that would have otherwise been spent on more costly health care procedures.[3] Still others demonstrate the role of prescription drug coverage in

[1] See "Generic Drug Entry Prior to Patent Expiration: An FTC Study." Federal Trade Commission, July 2002.
[2] National Institutes of Health, "A Plan to Ensure Taxpayer Interests are Protected," NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected." Cited in *Pharmaceutical Industry Profile 2002."* Pharmaceutical Research and Manufacturers Association, www.phrma.org.
[3] See studies cited in *Pharmaceutical Industry Profile 2002,* chapter 1.

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improving availability of drug therapies to consumers. For example, a recent Congressional Budget Office report found that Medicare beneficiaries with employer-sponsored insurance take almost 25% more prescriptions than beneficiaries with no prescription drug coverage.[4]

Affordability of prescription drugs. Health plans recognize the value of these vital prescription medications in offering clinically sound, cost effective health care services to their members, and prescription drug benefits are a common feature of their benefit packages. However, prescription drugs are only valuable to those who can afford them. According to a recent PriceWaterhouseCoopers report, health benefits costs for large employers are expected to increase 13.7% this year. About one-fifth of this increased spending, 22%, can be explained by rising prescription drug expenditures.[5]

Role of generic drugs in promoting access to prescription medications. Increasing reliance on generic drugs is an effective way to mitigate rising prescription drug spending. It has been estimated that generic drugs cost 25% less than brand-name drugs when entering the market, declining to 60% of the price of the original drug by the end of two years.[6] Health plan Pharmacy and Therapeutics Committees make ongoing evaluations of the safety, efficacy, and therapeutic value of the drugs included on plan formularies and take advantage of opportunities to incorporate into these formularies generic drug alternatives to brand name drugs already selected for their formularies as these drugs become available. Building on these decisions, health plans implement programs that inform providers and patients about formulary changes that, when clinically appropriate for an individual patient, can reduce out-of-pocket prescription drug costs for members and contribute to efforts to keep premiums affordable. These programs improve patient care by ensuring that health plan enrollees have access to safe and effective prescription drugs.

AAHP believes that reforms such as those proposed in this rule can foster increased patient access to generic medications without jeopardizing the vital role that the pharmaceutical innovation, reflected in the development of brand name drugs, plays in our health care system. We urge the FDA move forward to refine the proposed rule and issue it in final form in order to promote more affordable prescription drugs for all Americans. I would be glad to respond to any questions raised by our comments. You may reach me at (202) 778-3259 or ddennett@aahp.org.

Sincerely,

Diana C. Dennett
Executive Vice President

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[4] "Issues in Designing a Prescription Drug Benefit for Medicare: A CBO Study." Congressional Budget Office, October 2002.

[5] PriceWaterhouseCoopers, "The Factors Fueling Rising Healthcare Costs." Prepared for the American Association of Health Plans, April 2002.

[6] www.gphaonline/about/generics.phtml.